IV

*(Informacije)*

# INFORMACIJE INSTITUCIJ, ORGANOV, URADOV IN AGENCIJ EVROPSKE UNIJE

## Povzetek sklepov Evropske unije o dovoljenjih za promet z zdravili od 1. junij 2012 do 30. junij 2012

*(Objavljeno v skladu s členom 13 ali členom 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta* [1]*)*

(2012/C 224/01)

[1] UL L 136, 30.4.04, str. 1.

— **Izdaja dovoljenja za promet (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): Odobrena**

| Datum sprejetja sklepa | Ime zdravila | INN (mednarodno nelastniško ime) | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Farmacevtska oblika | ATC (anatomsko terapevtska kemijska oznaka) | Datum obvestila |
|---|---|---|---|---|---|---|---|
| 15.06.2012 | Rienso | Ferumoksitol | Takeda Global Research and Development Centre (Europe) Ltd<br>61 Aldwych,<br>London WC2B 4AE,<br>United Kingdom | EU/1/12/774/001-002 | Rztopina za injiciranje | Pending | 20.06.2012 |

— **Izdaja dovoljenja za promet (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): Zavrnjena**

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 21.06.2012 | Folotyn | Allos Therapeutics Limited<br>71 Knowl Piece,<br>Wilbury Way,<br>Hitchin, Hertfordshire SG4 0TY,<br>United Kingdom | — | 25.06.2012 |

— **Sprememba dovoljenja za promet (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): Odobrena**

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 01.06.2012 | Osigraft | Olympus Biotech International Limited<br>Raheen Business Park,<br>Limerick,<br>Ireland | EU/1/01/179/001 | 05.06.2012 |
| 11.06.2012 | Levetiracetam Teva | Teva Pharma B.V.<br>Computerweg 10,<br>3542 DR Utrecht,<br>Nederland | EU/1/11/701/001-032 | 13.06.2012 |
| 11.06.2012 | Mycophenolate mofetil Teva | Teva Pharma B.V.<br>Computerweg 10,<br>DR Utrecht 3542,<br>Nederland | EU/1/07/439/001-006 | 13.06.2012 |
| 11.06.2012 | Myfenax | Teva Pharma B.V.<br>Computerweg 10,<br>DR Utrecht 3542,<br>Nederland | EU/1/07/438/001-006 | 13.06.2012 |
| 14.06.2012 | Nivestim | Hospira UK Limited Queensway,<br>Royal Leamington Spa,<br>Warwickshire CV31 3RW,<br>United Kingdom | EU/1/10/631/001-009 | 18.06.2012 |
| 14.06.2012 | Quadramet | CIS bio international Boite Postale 32 - F-91192 Gif-sur-Yvette - France | EU/1/97/057/001 | 18.06.2012 |
| 15.06.2012 | Abseamed | Medice Arzneimittel Pütter GmbH & Co KG<br>Kuhloweg 37,<br>D-58638 Iserlohn,<br>Deutschland | EU/1/07/412/001-052 | 19.06.2012 |
| 15.06.2012 | Azopt | Alcon Laboratories (UK) Ltd.<br>Pentagon Park,<br>Boundary Way,<br>Hemel Hempstead,<br>Herts HP2 7UD,<br>United Kingdom | EU/1/00/129/001-003 | 20.06.2012 |

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 15.06.2012 | Epivir | ViiV Healthcare UK Ltd<br>980 Great West Road,<br>Brentford,<br>Middlesex,<br>TW8 9GS,<br>United Kingdom | EU/1/96/015/002 | 20.06.2012 |
| 15.06.2012 | Evra | Janssen-Cilag International NV<br>Turnhoutseweg,<br>30 - 2340 Beerse -<br>België | EU/1/02/223/001-003 | 19.06.2012 |
| 15.06.2012 | Optimark | Covidien Deutschland GmbH<br>Gewerbepark 1,<br>Neustadt/Donau 93333,<br>Deutschland | EU/1/07/398/001-014 | 19.06.2012 |
| 15.06.2012 | Prevenar | Wyeth-Lederle Vaccines S.A.<br>Pleainlaan 17 Boulevard de la Plaine,<br>1050 Brussels - Bruxelles,<br>Belgium | EU/1/00/167/001-008 | 20.06.2012 |
| 15.06.2012 | Temozolomide HEXAL | HEXAL AG<br>Industriestrasse 25,<br>D-83607 Holzkirchen,<br>Deutschland | EU/1/10/616/001-036 | 20.06.2012 |
| 15.06.2012 | Temozolomide Sandoz | Sandoz Pharmaceuticals GmbH<br>Raiffeisenstraße 11,<br>83607 Holzkirchen,<br>Deutschland | EU/1/10/617/001-002<br>EU/1/10/617/005-006<br>EU/1/10/617/009-010<br>EU/1/10/617/013-014<br>EU/1/10/617/017-018<br>EU/1/10/617/021-022<br>EU/1/10/617/025-036 | 20.06.2012 |
| 18.06.2012 | Atriance | Glaxo Group Limited<br>Berkeley Avenue, Greenford,<br>Middlesex UB6 0NN,<br>United Kingdom | EU/1/07/403/001 | 21.06.2012 |
| 18.06.2012 | Binocrit | Sandoz GmbH<br>Biochemiestrasse 10,<br>Kundl 6250,<br>Österreich | EU/1/07/410/001-052 | 21.06.2012 |
| 18.06.2012 | Epoetin alfa Hexal | Hexal AG.<br>Industriestrasse 25,<br>D-83607 Holzkirchen,<br>Deutschland | EU/1/07/411/001-052 | 21.06.2012 |
| 18.06.2012 | GILENYA | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/11/677/001-005 | 20.06.2012 |

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 18.06.2012 | GILENYA | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham, West Sussex RH12 5AB,<br>United Kingdom | EU/1/11/677/001-005 | 22.06.2012 |
| 18.06.2012 | Soliris | Alexion Europe S.A.S.<br>25, boulevard<br>de l'Amiral Bruix,<br>75016 Paris,<br>France | EU/1/07/393/001 | 20.06.2012 |
| 18.06.2012 | Soliris | Alexion Europe S.A.S.<br>25, boulevard<br>de l'Amiral Bruix,<br>75016 Paris,<br>France | EU/1/07/393/001 | 20.06.2012 |
| 21.06.2012 | alli | Glaxo Group Limited<br>Glaxo Wellcome House, Berkeley Avenue,<br>Greenford, Middlesex UB6 0NN,<br>United Kingdom | EU/1/07/401/007-016 | 25.06.2012 |
| 21.06.2012 | Cimzia | UCB Pharma SA.<br>Allée de la Recherche 60,<br>1070 Bruxelles,<br>Belgique/Researchdreef,<br>60, Brussel 1070,<br>België | EU/1/09/544/001-002 | 20.06.2012 |
| 21.06.2012 | Ketek | Aventis Pharma S.A.<br>20 avenue Raymond Aron,<br>F-92160 Antony,<br>France | EU/1/01/191/001-005 | 25.06.2012 |
| 21.06.2012 | Tarceva | Roche Registration Limited<br>6 Falcon Way,<br>Shire Park,<br>Welwyn Garden City,<br>AL7 1TW,<br>United Kingdom | EU/1/05/311/001-003 | 25.06.2012 |
| 21.06.2012 | Yervoy | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park,<br>Sanderson Road,<br>Uxbridge UB8 1DH,<br>United Kingdom | EU/1/11/698/001-002 | 25.06.2012 |
| 27.06.2012 | Abraxane | Celgene Europe Limited<br>1 Longwalk Road,<br>Stockley Park, Uxbridge,<br>Middlesex, UB11 1DB,<br>United Kingdom | EU/1/07/428/001 | 02.07.2012 |

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 27.06.2012 | Actraphane | Novo Nordisk A/S<br>Novo Allé,<br>DK-2880 Bagsvaerd,<br>Danmark | EU/1/02/229/001-004<br>EU/1/02/229/036-037 | 29.06.2012 |
| 27.06.2012 | Actrapid | Novo Nordisk A/S<br>Novo Allé,<br>DK-2880 Bagsvaerd,<br>Danmark | EU/1/02/230/001-004<br>EU/1/02/230/016-017 | 29.06.2012 |
| 27.06.2012 | Avastin | Roche Registration Limited<br>6 Falcon Way,<br>Shire Park,<br>Welwyn Garden City,<br>AL7 1TW,<br>United Kingdom | EU/1/04/300/001-002 | 02.07.2012 |
| 27.06.2012 | Cimzia | UCB Pharma SA.<br>Allée de la Recherche 60,<br>1070 Bruxelles,<br>Belgique/Researchdreef,<br>60, Brussel 1070,<br>België | EU/1/09/544/001-002 | 29.06.2012 |
| 27.06.2012 | Dificlir | Astellas Pharma Europe B.V.<br>Elisabethhof 19,<br>2353 EW Leiderdorp,<br>Nederland | EU/1/11/733/001-004 | 29.06.2012 |
| 27.06.2012 | Humira | Abbott Laboratories Ltd<br>Abbott House,<br>Vanwall Business Park,<br>Vanwall Road,<br>Maidenhead,<br>Berkshire SL6 4XE,<br>United Kingdom | EU/1/03/256/001-010 | 02.07.2012 |
| 27.06.2012 | Insulatard | Novo Nordisk A/S<br>Novo Allé,<br>DK-2880 Bagsvaerd,<br>Danmark | EU/1/02/233/003-004<br>EU/1/02/233/017 | 02.07.2012 |
| 27.06.2012 | Invanz | Merck Sharp & Dohme Ltd<br>Hertford Road,<br>Hoddesdon,<br>Hertfordshire EN11 9BU,<br>United Kingdom | EU/1/02/216/001-002 | 29.06.2012 |
| 27.06.2012 | Invega | Janssen-Cilag International NV<br>Turnhoutseweg, 30 -<br>2340 Beerse -<br>België | EU/1/07/395/001-095 | 02.07.2012 |

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|---|---|---|---|---|
| 27.06.2012 | Invirase | Roche Registration Limited<br>6 Falcon Way,<br>Shire Park,<br>Welwyn Garden City,<br>AL7 1TW,<br>United Kingdom | EU/1/96/026/001-002 | 29.06.2012 |
| 27.06.2012 | Irbesartan HCT Zentiva (Ex-Winthrop) | Sanofi<br>54, rue La Boétie,<br>75008 Paris,<br>France | EU/1/06/377/001-034 | 03.07.2012 |
| 27.06.2012 | Javlor | Pierre Fabre Médicament<br>45, place Abel Gance,<br>F-92100 Boulogne,<br>France | EU/1/09/550/001-012 | 02.07.2012 |
| 27.06.2012 | Karvezide | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park,<br>Sanderson Road,<br>Uxbridge UB8 1DH,<br>United Kingdom | EU/1/98/085/001-034 | 29.06.2012 |
| 27.06.2012 | Lucentis | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/06/374/001 | 29.06.2012 |
| 27.06.2012 | Menveo | Novartis Vaccines and Diagnostics S.r.l.<br>Via Fiorentina, 1,<br>53100 Siena,<br>Italia | EU/1/10/614/001-003 | 29.06.2012 |
| 27.06.2012 | Mixtard | Novo Nordisk A/S<br>Novo Allé,<br>DK-2880 Bagsvaerd,<br>Danmark | EU/1/02/231/001-004<br>EU/1/02/231/036-037 | 02.07.2012 |
| 27.06.2012 | Nexavar | Bayer Pharma AG<br>13342 Berlin,<br>Deutschland | EU/1/06/342/001 | 02.07.2012 |
| 27.06.2012 | Osseor | Les Laboratoires Servier<br>50, rue Carnot,<br>92284 Suresnes cedex,<br>France | EU/1/04/287/001-006 | 02.07.2012 |

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|---|---|---|---|---|
| 27.06.2012 | PREZISTA | Janssen-Cilag International NV<br>Turnhoutseweg, 30 -<br>2340 Beerse -<br>België | EU/1/06/380/001-005 | 02.07.2012 |
| 27.06.2012 | Protaphane | Novo Nordisk A/S<br>Novo Allé,<br>DK-2880 Bagsvaerd,<br>Danmark | EU/1/02/234/003-004<br>EU/1/02/234/017 | 02.07.2012 |
| 27.06.2012 | Protelos | Les Laboratoires Servier<br>50, rue Carnot,<br>92284 Suresnes cedex,<br>France | EU/1/04/288/001-006 | 02.07.2012 |
| 27.06.2012 | Rebif | Merck Serono Europe Limited<br>56, Marsh Wall,<br>London E14 9TP,<br>United Kingdom | EU/1/98/063/001-019 | 29.06.2012 |
| 27.06.2012 | Revolade | GlaxoSmithKline Trading Services Limited<br>6900 Cork Airport Business Park,<br>Kinsale Road,<br>Cork,<br>Ireland | EU/1/10/612/001-006 | 02.07.2012 |
| 27.06.2012 | Stocrin | Merck Sharp & Dohme Ltd<br>Hertford Road,<br>Hoddesdon,<br>Hertfordshire EN11 9BU,<br>United Kingdom | EU/1/99/111/001-005<br>EU/1/99/111/008<br>EU/1/99/111/010-011 | 02.07.2012 |
| 27.06.2012 | Sustiva | Bristol-Myers Squibb Pharma EEIG<br>Uxbridge Business Park,<br>Sanderson Road,<br>Uxbridge UB8 1DH,<br>United Kingdom | EU/1/99/110/001-005<br>EU/1/99/110/008-010 | 02.07.2012 |
| 27.06.2012 | Sycrest | N.V. Organon<br>Kloosterstraat 6, 5349 AB Oss,<br>Nederland | EU/1/10/640/001-006 | 02.07.2012 |
| 27.06.2012 | Synagis | Abbott Laboratories Ltd<br>Abbott House,<br>Vanwall Business Park,<br>Vanwall Road,<br>Maidenhead,<br>Berkshire SL6 4XE,<br>United Kingdom | EU/1/99/117/001-002 | 29.06.2012 |

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 27.06.2012 | Tasigna | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/07/422/001-012 | 02.07.2012 |
| 27.06.2012 | Temodal | Merck Sharp & Dohme Limited<br>Hertford Road,<br>Hoddesdon,<br>Hertfordshire, EN11 9BU,<br>United Kingdom | EU/1/98/096/001-025 | 02.07.2012 |
| 27.06.2012 | Trisenox | Cephalon Europe<br>5 Rue Charles Martigny,<br>94700 Maisons Alfort,<br>Cedex,<br>France | EU/1/02/204/001 | 02.07.2012 |
| 27.06.2012 | Viracept | Roche Registration Limited<br>6 Falcon Way,<br>Shire Park,<br>Welwyn Garden City,<br>AL7 1TW,<br>United Kingdom | EU/1/97/054/001<br>EU/1/97/054/004-005 | 29.06.2012 |
| 27.06.2012 | VPRIV | Shire Pharmaceuticals Ireland Limited<br>5 Riverwalk,<br>Citywest Business Campus,<br>Dublin 24,<br>Ireland | EU/1/10/646/001-006 | 02.07.2012 |
| 27.06.2012 | Xeplion | Janssen-Cilag International NV<br>Turnhoutseweg 30,<br>B-2340 Beerse,<br>België | EU/1/11/672/001-006 | 02.07.2012 |
| 27.06.2012 | Zeffix | Glaxo Group Ltd.<br>Greenford Road,<br>Greenford,<br>Middlesex UB6 0NN,<br>United Kingdom | EU/1/99/114/003 | 02.07.2012 |
| 27.06.2012 | Zypadhera | Eli Lilly Nederland B.V.<br>Grootslag 1-5,<br>NL-3991 RA Houten,<br>Nederland | EU/1/08/479/001-003 | 29.06.2012 |

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 27.06.2012 | Zyprexa | Eli Lilly Nederland B.V.<br>Grootslag 1-5,<br>3991 RA Houten,<br>Nederland | EU/1/96/022/002<br>EU/1/96/022/004<br>EU/1/96/022/006<br>EU/1/96/022/009-012<br>EU/1/96/022/014<br>EU/1/96/022/016-017<br>EU/1/96/022/019-040 | 29.06.2012 |
| 27.06.2012 | Zyprexa Velotab | Eli Lilly Nederland B.V.<br>Grootslag 1-5,<br>3991 RA Houten,<br>Nederland | EU/1/99/125/001-020 | 29.06.2012 |
| 28.06.2012 | CoAprovel | Sanofi Pharma Bristol-Myers Squibb SNC<br>54, rue La Boétie,<br>75008 Paris,<br>France | EU/1/98/086/001-034 | 03.07.2012 |
| 28.06.2012 | Copalia HCT | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/09/575/001-060 | 03.07.2012 |
| 28.06.2012 | Dafiro HCT | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/09/574/001-060 | 03.07.2012 |
| 28.06.2012 | Ecalta | Pfizer Limited<br>Ramsgate Road,<br>Sandwich,<br>Kent CT13 9NJ,<br>United Kingdom | EU/1/07/416/001-002 | 03.07.2012 |
| 28.06.2012 | ellaOne | Laboratoire HRA Pharma<br>15, rue Béranger,<br>75003 Paris,<br>France | EU/1/09/522/001 | 03.07.2012 |
| 28.06.2012 | Exforge | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/06/370/001-039 | 03.07.2012 |

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 28.06.2012 | Firmagon | Ferring Pharmaceuticals A/S<br>Kay Fiskers Plads 11,<br>Copenhagen S 2300,<br>Danmark | EU/1/08/504/001-003 | 07.07.2012 |
| 28.06.2012 | GONAL-f | Merck Serono Europe Ltd.<br>56, Marsh Wall,<br>London E14 9TP,<br>United Kingdom | EU/1/95/001/001<br>EU/1/95/001/003-005<br>EU/1/95/001/009<br>EU/1/95/001/012<br>EU/1/95/001/021-022<br>EU/1/95/001/025-028<br>EU/1/95/001/031-035 | 03.07.2012 |
| 28.06.2012 | Icandra | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/08/484/001-018 | 03.07.2012 |
| 28.06.2012 | Imprida | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/06/373/001-039 | 03.07.2012 |
| 28.06.2012 | Insulin Human Winthrop | Sanofi-Aventis Deutschland GmbH<br>D-65926 Frankfurt am Main,<br>Deutschland | EU/1/06/368/001-015<br>EU/1/06/368/020-024<br>EU/1/06/368/029-033<br>EU/1/06/368/037-042<br>EU/1/06/368/047-051<br>EU/1/06/368/056-057<br>EU/1/06/368/088-102<br>EU/1/06/368/113-150<br>EU/1/06/368/163-174 | 04.07.2012 |
| 28.06.2012 | Jalra | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/08/485/001-011 | 03.07.2012 |
| 28.06.2012 | Lamivudine Teva Pharma B.V. | Teva Pharma B.V.<br>Computerweg 10,<br>3542 DR Utrecht,<br>Nederland | EU/1/09/596/001-014 | 03.07.2012 |
| 28.06.2012 | Myclausen | Herbert J. Passauer GmbH & Co. KG<br>Stubenrauchstrasse 33,<br>14167 Berlin,<br>Deutschland | EU/1/10/647/001-004 | 03.07.2012 |

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 28.06.2012 | Pradaxa | Boehringer Ingelheim International GmbH<br>Binger Strasse 173,<br>D-55216 Ingelheim am Rhein,<br>Deutschland | EU/1/08/442/001-014 | 03.07.2012 |
| 28.06.2012 | PritorPlus | Bayer Pharma AG<br>13342 Berlin,<br>Deutschland | EU/1/02/215/001-021 | 04.07.2012 |
| 28.06.2012 | Rasilez HCT | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex RH12 5AB,<br>United Kingdom | EU/1/08/491/001-080 | 03.07.2012 |
| 28.06.2012 | Rilonacept Regeneron | Regeneron UK Limited<br>40 Bank Street,<br>E14 5DS London,<br>United Kingdom | EU/1/09/582/001 | 04.07.2012 |
| 28.06.2012 | Riprazo HCT | Novartis Europharm Limited<br>Wimblehurst Road,<br>Horsham,<br>West Sussex, RH12 5AB,<br>United Kingdom | EU/1/11/680/001-080 | 03.07.2012 |
| 28.06.2012 | Siklos | ADDMEDICA<br>101, rue Saint Lazare,<br>Paris 75009,<br>France | EU/1/07/397/001-004 | 03.07.2012 |
| 28.06.2012 | Siklos | ADDMEDICA<br>101, rue Saint Lazare,<br>Paris 75009,<br>France | EU/1/07/397/001-004 | 03.07.2012 |
| 28.06.2012 | Sprimeo HCT | Novartis Europharm Limited<br>Wimblehurst Road,<br>Horsham,<br>West Sussex, RH12 5AB,<br>United Kingdom | EU/1/11/683/001-080 | 02.07.2012 |
| 28.06.2012 | Vfend | Pfizer Ltd<br>Ramsgate Road,<br>Sandwich,<br>Kent CT 13 9NJ,<br>United Kingdom | EU/1/02/212/001-026 | 03.07.2012 |
| 28.06.2012 | Votubia | Novartis Europharm Limited<br>Wimblehurst Road,<br>Horsham,<br>West Sussex, RH12 5AB,<br>United Kingdom | EU/1/11/710/001-007 | 04.07.2012 |

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 28.06.2012 | Votubia | Novartis Europharm Limited<br>Wimblehurst Road,<br>Horsham,<br>West Sussex, RH12 5AB,<br>United Kingdom | EU/1/11/710/001-007 | 04.07.2012 |
| 28.06.2012 | Vyndaqel | Pfizer Specialty UK Limited<br>Ramsgate Road,<br>Sandwich,<br>Kent CT13 9NJ,<br>United Kingdom | EU/1/11/717/001 | 04.07.2012 |
| 28.06.2012 | Xiliarx | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex, RH12 5AB,<br>United Kingdom | EU/1/08/486/001-011 | 03.07.2012 |
| 28.06.2012 | Zomarist | Novartis Europharm Ltd<br>Wimblehurst Road,<br>Horsham,<br>West Sussex, RH12 5AB,<br>United Kingdom | EU/1/08/483/001-018 | 03.07.2012 |

— **Ukinitev dovoljenja za promet (člen 13 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta)**

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 28.06.2012 | Hexavac | Aventis Pasteur MSD<br>8, rue Jonas Salk,<br>69007 Lyon,<br>France | EU/1/00/147/001-012 | 04.07.2012 |

— **Izdaja dovoljenja za promet (člen 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta** [1]**): Odobrena**

| Datum sprejetja sklepa | Ime zdravila | INN (mednarodno nelastniško ime) | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Farmacevtska oblika | ATC (anatomsko terapevtska kemijska oznaka) | Datum obvestila |
|---|---|---|---|---|---|---|---|
| 14.06.2012 | Porcilis ColiClos | — | Intervet International B.V.<br>Wim de Körverstraat 35,<br>5831 AN Boxmeer,<br>Nederland | EU/2/12/141/001-009 | Suspenzija za injiciranje | QI09AB08 | 17.06.2012 |
| 15.06.2012 | Poulvac E. coli | — | Pfizer Limited<br>Ramsgate Road,<br>Sandwich, Kent,<br>CT13 9NJ,<br>United Kingdom | EU/2/12/140/001-008 | Liofilizat za suspenzijo za cepljenje s pršenjem za piščance | QI01AE04 | 20.06.2012 |

[1] UL L 136, 30.4.04, str. 1.

— **Sprememba dovoljenja za promet (člen 38 Uredbe (ES) št. 726/2004 Evropskega parlamenta in Sveta): Odobrena**

| Datum sprejetja sklepa | Ime zdravila | Imetnik dovoljenja za promet | Registracijska številka v registru Skupnosti | Datum obvestila |
|---|---|---|---|---|
| 11.06.2012 | Activyl | Intervet International B.V.<br>Wim de Körverstraat 35,<br>5831 AN Boxmeer,<br>Nederland | EU/2/10/118/001-021 | 13.06.2012 |
| 14.06.2012 | Emdocam | Emdoka bvba<br>J. Lijsenstraat 16,<br>B-2321 Hoogstraten,<br>België | EU/2/11/128/001-003 | 18.06.2012 |
| 27.06.2012 | Bovilis BTV8 | Intervet International B.V.<br>Wim de Körverstraat 35,<br>5831 AN Boxmeer,<br>Nederland | EU/2/10/106/001-014 | 02.07.2012 |
| 28.06.2012 | Nobilis IB 4-91 | Intervet International B.V.<br>Wim de Körverstraat 35,<br>5831 AN Boxmeer,<br>Nederland | EU/2/98/006/001-010 | 04.07.2012 |
| 28.06.2012 | Oxyglobin | OPK Biotech Netherlands BV<br>Teleportboulevard 140,<br>1043EJ Amsterdam,<br>Nederland | EU/2/99/015/001-002 | 04.07.2012 |

Kdor želi dobiti vpogled v javno poročilo o oceni zadevnih zdravil ter o zadevnih sklepih o zdravilih, se lahko obrne na naslov:

The European Medicines Agency
7, Westferry Circus,
Canary Wharf
UK - LONDON E14 4H